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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/775,181	02/01/2001	Gregory Donoho	LEX-0129-USA	7100

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LEXICON GENETICS INCORPORATED
8800 TECHNOLOGY FOREST PLACE
THE WOODLANDS, TX 77381-1160

EXAMINER

LI, RUIXIANG

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 08/14/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/775,181

Applicant(s)

DONOHO

Examiner

Ruixiang Li

Art Unit

1646

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 16 July 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.
- NOTE: _____.
3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 1-8.

Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER

Continuation of 5. does NOT place the application in condition for allowance because:

I. Claim rejection under 35 U.S.C. § 101

The rejection of Claims 1-4 under 35 U.S.C. § 101 stands. The newly added claims 5-8 are also rejected under 35 U.S.C. § 101. The instant specification fails to disclose sufficient information on the specific functions of the protein with the deduced amino acid sequence encoded by the claimed nucleic acid and thus fails to satisfy the utility requirement set forth under 35 U.S.C. § 101.

Applicants argue that the amino acid sequence deduced from the claimed nucleic acid sequence is related to GPCRs, members of which that are targets of currently marketed drugs and thus the claimed invention has a well-established utility. This has been fully considered but is not deemed to be persuasive because 35 U.S.C. 101 requires disclosure of a specific, substantial, and credible utility, or a well-established utility. Such a patentable utility has to be a "real world" context of use which does not require significant further research. The instant disclosure asserts that the deduced amino acid sequence encoded by the claimed nucleic acid has 7 hydrophobic transmembrane regions and shares structural similarity with GPCRs. Nonetheless, the disclosure fails to disclose the degree of homology with the GPCRs, and most importantly, fails to disclose the biological functions of the protein encoded by the claimed nucleic acid sequence. While it may be unnecessary to disclose ligands of the protein encoded by the claimed nucleic acid, it is required to disclose the functions of the claimed molecules to satisfy the utility requirement set forth under 35 U.S.C. § 101. In view of the diversity of structure and functions of the proteins, prediction of function using comparative sequence analysis may lead to the creation and propagation of assignment errors if not performed appropriately (See, Peer Bork and Eugene V. Koonin, Predicting functions from protein sequences--where are the bottlenecks? *Nature Genetics* 18:313-318, 1998). There are putative seven transmembrane molecules, which do not appear to be coupled to a G protein (Ji et al. G-protein-coupled receptors, *JBC*, 273:17299-17302, 1998).

Therefore, the information provided or "predicted" based upon sequence homology can only be used as guidance in determining ligands and functions of a molecule by experiments. Any functions predicted based upon the sequence homology will have to be confirmed ultimately by bench work. Such confirmation whether the claimed nucleic acid encodes a functional GPCR molecule requires undue experimentation. See *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966), noting that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion".

Applicants argue that the instant disclosure provides a patentable utility for the claimed invention citing the "device" case law. This has been fully considered but is not deemed to be persuasive because the "device" case law deals with "inoperativeness" under 101 (pertains to perpetual motion machines, for example). The claimed invention in the instant case is drawn to an isolated nucleic acid, not a device and the instant rejection under 35 USC 101 is not directed to inoperativeness, but to a lack of patentable utility of the claimed nucleic acid. Thus, applicants' argument citing a case law regarding a device is irrelevant to the instant case.

II. Claim Rejections Under 35 U. S. C. 112, 1st Paragraph

Claims 1-8 are rejected under 35 U. S. C. 112, 1st paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial, and credible utility, or a well-established utility, one skilled in the art clearly would not know how to use the claimed invention. The applicants' arguments about the patentable utility of the claimed invention has been fully considered but is not deemed to be persuasive for reason set for the above.

III. Claim Rejection Under 35 U. S. C. 112, second Paragraph

The rejection of Claim 2 under 35 U.S.C. 112, second paragraph remains. Claim 2 is rejected under 35 U.S.C. 112, 2nd paragraph because it is indefinite. Claim 2 recites "under highly stringent conditions", but without giving the specific conditions in the claim. Neither the specification nor the relevant literature provides an unambiguous definition for the term.

The applicants argue that the specification provides specific teaching regarding "highly stringent hybridization conditions" and that a claim need not describe the invention, such description being the role of the disclosure. This has been fully considered but is not deemed to be persuasive because the hybridization conditions need to be described unambiguously either in the specification or in the claim. In the instant case, such conditions are not recited in the claim whereas the specification only provides exemplary conditions for "highly stringent conditions" (Note the use of "e.g." at line 21 of page 7 of specification). Since neither the specification/claim nor the art provides a definition for the term, the claim is indefinite.

It is recommended that the conditions for hybridization be recited in the claim or be described unambiguously in the specification or that the term simply be deleted to overcome the rejection under 35 U. S. C. 112, second paragraph.